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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/876,773	06/07/2001	James E. Darnell JR.	600-1-195C	9919

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EXAMINER	
NOAKES, SUZANNE MARIE	
ART UNIT	PAPER NUMBER
1656	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/22/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/876,773	DARNELL ET AL.	
	Examiner	Art Unit	
	Suzanne M. Noakes, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 69-96* is/are pending in the application.

4a) Of the above claim(s) *1,69-79 and 81-96* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/07/2001*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group XI, claim 80, in the reply filed on 15 November 2006 is acknowledged. The requirement is deemed proper and is therefore made Final.

Status of the Application

2. Claims 1 and 69-96 are pending. Claims 1, 69-79 and 81-96 are withdrawn from consideration as they are drawn to non-elected subject matter. Claim 80 is subject to examination on the merits.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 07 June 2001 has been considered by the examiner. See signed and attached PTO-1449.

Specification

4. The disclosure is objected to because of the following informalities:

A. Cross-References to Related Applications should be updated in the first line of the specification (See 37 CFR 1.78 and MPEP § 201.11) to include that Application 08/212,185 has issued as US patent 6,605,442.

B. The description of Figure 13, p. 23, line 4, in the Brief Description of the Drawings was amended on 04 December 2003 to describe Figures 13A-C. It is

noted, however, that Figure 13D still exists and thus needs to be included in said description. Likewise, all references to said Figure 13A-C needs to be updated to 13A-D, for instance, p. 2 and 6 references and makes changes in specification to Figures 13A-C.

C. The description of Figure 23 on p. 26, lines 4-18 provides a single description of Figure 23 and does not differentiate and provide a description for Figures 23A and 23B.

Appropriate correction is required.

D. The description of p. 38 line 5, regarding the DNA molecule that encodes a 91 kDa protein according to Figure 2 (SEQ ID No: 3) or Figure 13 (SEQ ID No: 8). It is noted that SEQ ID No: 8 is an amino acid sequence and it appears that it should read Figure 13 (SEQ ID No: 7). The amendments to the specification filed 04 December 2003 does not remedy this inaccuracy.

Appropriate correction is required.

Claim Rejections - 35 USC § 112 – 2nd paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 80 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 80 is indefinite because it is drawn to a DNA molecule that hybridizes under "standard hybridization conditions". The standard conditions are not defined by the claim which reads on a full range of what can be considered as standard conditions, that is from very permissive to reasonably 'high' stringency. Although the specification contemplates certain standard conditions (page 35, lines 6-8) it does not provide a limited definition for ascertaining the requisite degree of standard conditions sought in the claim, e.g. salt, temperature, wash and/or hybridization time which are known to have significant impacts on the permissiveness of any hybridization experiment. Thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus the metes and bounds of the claim are ambiguous.

Double Patenting – Non-Statutory

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claim 80 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 7-11 of U.S. Patent No. 6,124,118. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 80 is generic to all that is recited in claims 1-4 and 7-11 of patent '118. That is, claims 1-4 and 7-11 of said patent fall entirely within the scope of claim 80 or, in other words, claim 80 is anticipated by claims 1-4 and 7-11 of patent '118.

Specifically, claim 80 of the instant application is drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) having the following characteristics: a) the RRF is cytoplasmic in origin, b) the RRF is activated by tyrosine phosphorylation and c) RRF is translocated to the nucleus of a target cell upon

activation; wherein said DNA molecule hybridizes under non-specified standard hybridization conditions to the nucleotide sequence of SEQ ID No: 3.

Claim 1 of patent '118 is drawn to a recombinant DNA molecule encoding a receptor recognition factor (RRF) wherein said DNA hybridizes under standard hybridization conditions of 5 x SSC and 65 °C to a nucleic acid selected from SEQ ID Nos: 1, 3, 5, 7, 9 and 11, all of which have the following characteristics: a) cytoplasmic in origin, b) activated by tyrosine phosphorylation and c) are translocated to the nucleus of a target cell upon activation. Dependent claim 2 of patent '118 specifically states that the nucleic acid is complementary to SEQ ID No: 3 and claims 3 and 4 operatively link the DNA to a control sequence and then place it in an expression vector. Claims 7-11 are encompassed by claim 1 and individually claim SEQ ID Nos: 1, 5, 7, 9 and 11, respectively.

A sequence alignment of the instant SEQ ID No: 3 with that of patented SEQ ID Nos: 1, 5, 7, 9 and 11 from '118 demonstrates that each sequence has sequence identities of 55, 100, 87, 60 and 59%, respectively (see Appendices A-E) with SEQ ID No: 3 of the instant claim 80. Therefore, it would be expected that these sequence all would be able to hybridize with SEQ ID No: 3 under the non-specified standard hybridization conditions recited in instant claim 80.

9. Claim 80 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15, 21-26 and 29-34 of U.S. Patent No. 5,976,835. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 80 is encompassed within the scope of the

patented claims 1-15, 21-26 and 29-34 and said patented claims would necessarily anticipate the pending claim 80.

The patented claims from '835 are drawn to three specific receptor recognition factors (RRF) termed Stat1 proteins (see also column 20, lines 53-67 to column 21, lines 1-57): (1) SEQ ID No: 3 is a DNA molecule that encodes a human Stat1α protein (SEQ ID No: 4) and is identical to SEQ ID No: 3 of the pending claim 80; (2) SEQ ID No: 7 is a DNA molecule that encodes a murine Stat1α protein (SEQ ID No: 8) that is 85% identical to SEQ ID NO:3 of the pending claim 80 and (3) SEQ ID No: 5 encodes a Stat1β protein (SEQ ID No: 6) which is a splice variant of SEQ ID No: 3, being 100% identical to the first 2607 nucleotides of SEQ ID NO:3 (see Appendices B and C).

The difference between the patented claims and pending claim 80 is the terminology and use of the term Stat1α or Stat1β. The patent defines each of these terms in the specification as described in the preceding paragraph. Furthermore, it is also apparent from dependent claim 5 that SEQ ID No: 3 *is* a Stat1α and thus it is encompassed in claims 1-4. Claim 7 differs by being drawn to different Stat1α or Stat1β proteins encoded by SEQ ID No: 7 and 5, respectively. However, as noted above, the nucleotide sequence identities are 85% and 100%, respectively, and thus would necessarily hybridize to the recombinant DNA molecule of pending claim 80. Dependent claims 10-15 differ from pending claim 80 by further defining specific embodiments of Stat1α or Stat1β proteins, e.g. they must possess highly charged C-terminus, an SH2 domain and an arginine that corresponds to amino acid 602 of SEQ ID No: 4. However, these are *all* inherent and necessary features of any RRF that is

functional. These features aid in phosphorylation and in activating the dimerization of the proteins (see column 46, lines 53-67 of patent '835). Thus in order to meet the requirements of a)-c) in pending claim 80, these features must be present in any RRF protein encoded by the recombinant DNA that can hybridize to SEQ ID No: 3.

Claims 21-24 differ from instant claim 80 by reciting additional sequences such as SEQ ID No: 7 and 5 and reciting the specific standard hybridization conditions. However, it is expected that these standard conditions are permissive enough to allow hybridization of all the claimed sequences based on the % nucleotide sequence identity of each as noted above.

Claims 29-34 differ from instant claim 80 by reciting that the recombinant DNA molecule is one that comprises at least 25 contiguous nucleotides selected from SEQ ID No: 3, 5 and 7 and again operatively linking said DNA to a control sequence and placing into an expression vector. It is asserted that these claims would still anticipate claim 80 because the comprising language allows for the entire sequences of SEQ ID No: 3, 5 and 7 and so said DNA would hybridize to instant claim 80 and produce a function RRF protein for the reasons state above.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne M. Noakes, Ph.D. whose telephone number is

571-272-2924. The examiner can normally be reached on Monday to Friday, 7.00am to 3.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Suzanne M. Noakes

SMN
15 December 2006